UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,972	01/15/2002	Andreas Peter Abel	2001_1861A	4434

513 7590 10/17/2006

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,972	ABEL ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63 and 81-92* is/are pending in the application.

4a) Of the above claim(s) *48-63 and 92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47 and 81-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 June 2006 has been entered.

Withdrawn Rejections

2. Previous rejections of claim under 35 USC 112, first paragraph have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international

application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Feldstein et al. (US 6,192,168).

Feldstein et al. teach a device comprising: a sensor platform having a planar optical waveguide (col. 5, lines 47-48, 310, Fig. 10); a sealing layer forming a tight seal, either directly or with a sealing medium, with the planar optical waveguide (col. 8, lines 30-51); a plurality of open recesses opening at least towards the sensor platform, which form a corresponding plurality of sample compartments in a two-dimensional arrangement (col. 10, lines 35-40; 108, Fig. 8a and 8b, multi-channels form a two-dimensional arrangement); each of the sample compartments has different biological recognition elements for specific recognition and binding of different analytes immobilized in more than five discrete measurement areas in a two-dimensional array on the planar waveguide (A-F, Fig. 8b, show each different immobilized biological recognition element and the two-dimensional array of measurement areas in each sample compartment which is a channel, col. 9, lines 49-58, molecular species specific for different analyte indicates different biological recognition elements); the measurement areas are in optical interaction with excitation light emanating from the optical waveguide as part of the sensor platform which forms a demarcation of the sample compartments (col. 7, lines 24-37); and the sample compartments are operable such that sample or reagent solutions are clearable or can be supplied thereto (inlets 306 and outlets 308, Fig. 9, are used to supply and clear reagents and samples).

5. Claims 1-34, 38-40, 42-47, 81-84 and 86-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Neuschäfer et al. (WO 96/35940).

Neuschäfer et al. teach a device comprising: a sensor platform having a planar optical waveguide (pg. 13, last paragraph-pg. 14, line 4), and a sealing layer forming a tight

seal with a sealing medium with the planar optical waveguide (a cover is part of a sealing layer that is glued to the sensor platform to form a unit, pg. 29, lines 1-17; pg. 13, last paragraph-pg. 14, line 5); a plurality of recesses opening at least towards the sensor platform (a cover which is part of the sealing layer has recesses, central cut out portions, comprising inlet and outlet openings for solutions, pg. 14, lines 6-12), each of the recesses forming a corresponding sample compartment in a 2-dimensional arrangement (central cut out portions form a flowthrough cell, which is the sample compartment, the sample compartments are formed in a 2-dimensional arrangement, pg. 14, lines 6-12, 7, Fig. 5b), wherein each of the sample compartments comprise different biological recognition elements, for specific recognition and binding of different analyte (pg. 14, lines 11-12; pg. 21, lines 19-24; immobilized recognition elements that are specific to different analyte indicates that the recognition elements are different, pg. 13, lines 11-16; pg. 8, lines 22-24; pg. 18, lines 3-6; pg. 34, line 26-pg. 25, line 5; pg. 45, lines 3-5) and are immobilized in 5 to 50 discrete measurement areas, which encompasses the recited five or more, in a two-dimensional array on the planar optical waveguide (number of individual waveguiding regions, pg. 13, lines 7-8; recognition elements immobilized on waveguiding regions, pg. 14, lines 11-12; detection regions, pg. 13, lines 21-22), the measurement areas are in optical interaction with an excitation light emanating from the optical waveguide as part of the sensor platform which forms a demarcation of the sample compartments (pg. 7, lines 18-19; pg. 8, lines 22-24; pg. 17, lines 5-6), wherein the sample compartments are operable such that samples received therein are removable therefrom and further sample solutions are receivable therein (outlet indicates that samples are removable and further samples are receivable, pg. 14, lines 8-10).

Regarding claims 2 and 3, Neuschäfer et al. teach one measurement area in each of the sample compartments used for referencing (quality control, pg. 36, lines 23-24).

Neuschäfer et al. also teach the referencing measurement areas reference same chemical parameters in a number of sample compartments distributed over the sensor platform (same control molecules, used for referencing, are immobilized in strips on five regions, pg. 36, lines 25-26). Neuschäfer et al. do not specifically teach lateral distribution of the chemical parameters over the sensor platform. However, such a limitation is drawn to intended use of referencing measurement areas and do not require any further product limitations. Therefore, since the device of Neuschäfer et al. comprise the limitations recited in claims 1 and 2, the device of Neuschäfer et al. would be capable of providing such determination of chemical parameters.

With respect to claim 4, Neuschäfer et al. teach measurement areas in optical interaction with an evanescent field of the excitation light guided in the planar optical waveguide (pg. 6, last line-pg. 7, line 3).

Regarding claims 5 and 6, Neuschäfer et al. teach the planar optical waveguide being self-supporting (pg. 5, lines 24-29) and part of the sensor platform being a multi-mode or single-mode waveguide comprising glass (pg. 15, line 10), which is optically transparent at the excitation wavelength (pg. 15, lines 13-14).

With respect to claims 7-13, Neuschäfer et al. teach the planar optical film waveguide comprising a first optically transparent layer, a waveguiding layer, on a second optically transparent layer, made of glass, wherein the second optically transparent layer has a lower refractive index than the first layer (pg. 10, lines 12-17; pg. 15, lines 19-22) and wherein the refractive index of the first optically transparent layer is higher than 2.0 (pg. 16, lines 2-3), which encompasses the recited greater than 1.8, and is made of TiO_2 (pg. 15, lines 4-5). Neuschäfer et al. also teach the thickness of the first optically transparent layer between 40 and 1000 nm (pg. 15, lines 7-8), which encompasses the recited between 40 and 300 nm. Neuschäfer et al. also teach an additional optically

transparent layer located between the first and second optically transparent layers, and in contact with the first optically transparent layer (substrate is covered with thin layer, which indicates contact, pg. 15, lines 18-20), and having a thickness of less than 10,000 nm (pg. 15, lines 17-18), which encompasses the recited range of 5-10,000 nm, wherein the purpose of the additional layer is to reduce the surface roughness below the first optically transparent layer (pg. 15, lines 18-22).

Regarding claims 14-16, Neuschäfer et al. teach an the device further comprising an adhesion-promoting layer deposited on the first optically transparent layer for the immobilizing biological recognition elements (pg. 19, lines 14-16), having a thickness of less than 50 nm (pg. 19, lines 17-18), which is encompassed by the recited less than 200 nm, and a comprising chemical compounds of silanes (pg. 12, lines 15-20).

With respect to claims 17-18 and 81, Neuschäfer et al. teach measurement areas generated by deposition of biological elements on the sensor platform (Fig. 3-5; pg. 13, last paragraph-pg. 14, line 2; pg. 18, lines 12-13). Although Neuschäfer et al. do not specifically teach the areas generated by deposition of biological recognition elements, such a limitation does not appear to physically further limit the product recited in claims 1 and 17. It is unclear what product limitations are set forth by areas generated by laterally selective deposition, and since the same product limitations are taught by Neuschäfer et al. as recited in claims 1 and 17, the product of Neuschäfer et al. would be capable of comprising measurement areas generated by deposition of biological elements. Neuschäfer et al. teach a method of deposition comprising ink jet spotting (pg. 18, lines 15-21).

Regarding claims 19 and 20, Neuschäfer et al. teach a biological recognition element being nucleic acids (pg. 21, lines 19-24), including DNA which comes from a cell and is considered a cell fragment.

With respect to claims 21-22, Neuschäfer et al. teach "chemically neutral" compounds such as bovine serum albumin, to minimize nonspecific binding (pg. 37, lines 23-29; pg. 40, lines).

Regarding claims 23-26, Neuschäfer et al. teach the first optically transparent layer having at least one grating structure formed therein for incoupling excitation light to the measurement areas (pg. 16, lines 22-25), and the first optically transparent layer having at least one grating structure formed therein for outcoupling of light into the first optically transparent layer (pg. 17, lines 5-13). Neuschäfer et al. also teach the incoupling and out coupling grating structures interchangeable with respect to incoupling and outcoupling (pg. 17, lines 6-7).

With respect to claims 27-29, Neuschäfer et al. teach grating structures having a period of 200 nm – 1000 nm and a grating modulation depth of 3-100 nm (pg. 16, last paragraph), wherein the ration of the grating modulation dept to thickness of the first optically transparent layer is equal to or smaller than 0.2 (pg. 16, lines 11-12). Neuschäfer et al. further teach grating structures being rectangular with a periodic modulation of the refractive index in the planar optically transparent layer (rectangular, pg. 16, lines 16-17).

Regarding claim 30, Neuschäfer et al. teach a thin metal layer, gold, deposited between the first optically transparent layer and the immobilized biological recognition elements, wherein the thickness of the metal can be excited at a luminescence wavelength (pg. 11, lines 11-15).

With respect to claims 31-34, Neuschäfer et al. teach a grating structure having a diffractive grating with a uniform period (pg. 16, last paragraph) or a multi-diffractive grating (1-3 modes is a multi-diffractive grating, pg. 18, lines 1-2). Neuschäfer et al. further teach the incoupling and outcoupling grating structures located outside a region of the sample compartments (grating located in and out of sample compartment, 3,3', Fig. 6;

pg. 9, lines 23-24) and grating structures extend over at least a portion of the sample compartments (one periodicity indicates one grating structure over all sample compartments; pg. 16, last paragraph).

Regarding claims 38, 39, 82 and 83, Neuschäfer et al. teach a sealing material, comprising polysiloxane (pg. 12, lines 15-20), and is self-adhesive (pg. 34, lines 4-7).

With respect to claims 40, 42, 84 and 86, Neuschäfer et al. teach 2-100 measurement areas in one sample compartment (pg. 13, lines 22-23), which is encompassed by the recited 2-1000 measurement areas. Neuschäfer et al. also teach the sample compartments having a volume of 0.07 ml (pg. 34, line 5), which is encompassed by the recited 100 nl-1ml.

Regarding claims 43 and 87, Neuschäfer et al. the device comprising sample compartments closed at a side facing away from the sensor platform except for inlet and outlet openings for sully and removal of samples (Fig. 5b; pg. 14, lines 6-12). Neuschäfer et al. fail to teach supply or removal of samples performed in a closed flow-through system, wherein common inlet and outlet openings are addressed row by row or column by column. However, such limitations do not appear to further limit the product limitations recited in claims 1, 43 and 87. Therefore, since Neuschäfer et al. teach the product limitations recited in claims 1, 43 and 87, the device of Neuschäfer et al. would be capable of performing such supply or removal of samples.

With respect to claims 44 and 88, Neuschäfer et al. fail to teach supply of samples affected by pressure differences or electric potentials. However, such a limitation does not appear to provide further product limitations to the product of claims 1 and 44. Therefore since Neuschäfer et al. teach the recited product limitations of claims 1 and 44, the device of Neuschäfer et al. would be capable of affecting the sample supply with the recited pressure differences or electric potentials.

Regarding claims 45-47 and 89-91, Neuschäfer et al. teach sample compartments having openings for locally addressed supply or removal of samples or other reagents at the side facing away from the sensor platform (inlet and outlet openings for solutions, pg. 14, lines 6-12). Neuschäfer et al. further teach compartments provided for reagents (reagents are contained in a compartment when introduced into the flow-through device, pg. 36, lines 8-10). Neuschäfer et al. also teach mechanically recognizable marks are provided on the sensor platform, in order to facilitate the adjustment in an optical system (depression cut for waveguide so waveguiding layer faces the cannels and facilitates optical detection, pg. 37, lines 7-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al., as applied to claim 1, in view of Hashimoto et al. (US 6,480,639).

Neuschäfer et al., as applied to claim 23, teach a device comprising a tight sealing layer, but fail to teach the material being optically transparent or optically absorbent.

Hashimoto et al. teach a sealing layer being optically transparent or absorbent (col. 16, lines 54-63), in order to block leakage lights from the light emitting device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al., an absorbent or transparent sealing layer as taught by Hashimoto et al., in order to more effectively seal the optical device and fix optical fibers.

Hashimoto et al. also teach a 2 layer system wherein a first layer that is transparent to excitation radiation is brought into contact with a sensor platform (col. 16, line 54-57), and a second layer absorbent in a spectral range of the excitation radiation is present and located remotely from the sensor platform (col. 16, lines 58-63).

7. Claims 41 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940).

Neuschäfer et al., as applied to claim 1, teach a device comprising a sample compartment occupying an area of 9 mm^2 (pg. 36, last 2 lines). Neuschäfer et al. fail to teach an area of 0.001-6 mm^2. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 41 and 85 are for any particular purpose or solve any stated problem, and the prior art teaches that the measurement area can be varied in order to accommodate different sample

volumes, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the flow-through device art.

Response to Arguments

8. Previous rejections under 35 USC 112, first paragraph and 35 USC 112, second paragraph have been withdrawn in light of applicant's arguments and amendments.

9. Applicant's arguments filed 29 June 2006 have been fully considered but they are not persuasive. Applicant argues that Neuschäfer et al. fail to teach each of the strip-like waveguiding regions having recognition elements immobilized in a two-dimensional array. In response to applicant's argument, the strip-like waveguiding regions are considered a two-dimensional array because a plurality of regions are present and the array has both a length and width dimension and is therefore two-dimensional.

Applicant further argues that while Neuschäfer et al. discloses there are a number of suitable choices for the recognition elements, there is not suggestion that each of the strip-like waveguiding regions has different biological recognition elements immobilized in five or more discrete measurement areas. Applicant's argument is not persuasive because while Neuschäfer et al. do not specifically disclose which different biological recognition elements are immobilized at each measurement area, Neuschäfer et al. discloses biological recognition element specific to different analyte immobilized in each measurement area at page 13, lines 11-16; page 18, lines 22-24; page 18, lines 3-6; pg. 34, line 26 – page 25, line 5 and page 45, lines 3-5. Biological recognition elements immobilized in each measurement area are specific to a different analyte indicates that different biological recognition elements are immobilized in region to bind specifically to different analyte.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE 09/29/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600